K103726

FEB - 8 2012

INTEGRA
LIMIT UNCERTAINTY

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York, Pa 17402
Phone (717) 940-8335
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510(k) Summary

Submitted by: Integra York PA, Inc.
589 Davies Drive, York, PA 17402 USA

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Integra York PA, Inc.
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Date Prepared: January 31, 2012

Device Trade Name: Integra™ Jarit® Take-Apart Endoscopic Instruments

Device Common Name: Endoscopic Instruments

Classification Name: Coagulator-Cutter, Endoscopic, Unipolar (and Accessories)

Device Class: Class II

Product Code: KNF

CFR Classification: 21 CFR 884.4160

Subsequent Product Code: GEI

Subsequent CFR Classif. : 21 CFR 878.4400

Device Description:
Integra™ Jarit® Take-Apart Endoscopic Instruments easily separate into three components - insert, shaft, and handle. Inserts include graspers, dissectors, scissors, biopsy forceps and specialized spoon forceps. Inserts connect to either a 5mm or 10mm diameter shaft with lengths of 350mm or 425mm; inserts and shaft connect to monopolar handles which are available with/without rotation or ratchets. The reusable devices are packaged non-sterile and are steam sterilizable.

Indications For Use:
Integra™ Jarit® Take-Apart Endoscopic Instruments are intended for use in laparoscopic gynecologic surgery and other operative procedures under endoscopic observations. For use when a rigid endoscopic instrument for grasping, dissecting and/or other manipulation of soft tissue is determined to be appropriate by the surgeon. For those instruments with electrosurgical capability, current can be used for coagulation and/or cutting.

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Predicate Devices:

510(k) #	Device	Manufacturer	Product Code
K932456	Jarit Surgical Instruments	Integra York PA, Inc.	KNF
K010752	Aesculap Modular Endo. Instr.	Aesculap, Inc.	KNF
K103282	Laparoscopic Dissector	Applied Medical Resources	GEI
K962119	Re-New Laparoscopic Instr,	Microline Surgical, Inc.	GEI
K043013	Miltex Laparoscopic Instr.	Miltex, Inc.	HET

Refer to attached predicate comparison charts 5-1A and 5-1B.

Performance Standards:

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, the Integra™ Jarit® Take-Apart Endoscopic Instruments conform to the following standards:

- IEC-60601-2-2: *Medical electrical equipment – Part 2-2: Particular requirements for the safety of high frequency surgical equipment*
- ANSI/AAMI ST79:2006/A2:2009: *Steam Sterilization and Sterility Assurance in Health Care Facilities*
- ANSI/AAMI ST77:2006: Containment Devices for Reusable Medical Devices Sterilization
- ANSI/AAMI ST8:2008: Hospital Steam Sterilizers
- AAMI TIR12:2004: Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities. A Guide for Device Manufacturers
- AAMI TIR30:2003: A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices
- AAMI ST81:2004: Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
- EN ISO 13402:2001: Surgical and dental hand instruments, Determination of resistance against autoclaving, corrosion and thermal exposure
- DIN EN ISO 10993-4:2009-10: Biological evaluation of medical device – Part 4: Selection of tests for interactions with blood
- DIN EN ISO 10993-5:2009-10: Biological evaluation of medical device – Part 5: Tests for in vitro Cytotoxicity
- ISO 10993-10:2010: Biological evaluation of medical devices—Part 10: Tests for Irritation and Skin Sensitization
- Reprocessing at 100 cycles per DIN EN 285:2009: Sterilization – Steam sterilizers – Large sterilizers

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Summary of Performance Data:

Testing Performed	Results
Manual Cleaning Validation (Spore Log Reduction) per AAMI TIR30:2003.	**Pass**
Mechanical Cleaning Validation (Spore Log Reduction) per AAMI TIR30:2003.	**Pass**
Manual Cleaning Validation (Protein Analyses) per AAMI TIR30:2003.	**Pass**
Mechanical Cleaning Validation (Protein Analyses) per AAMI TIR30:2003.	**Pass**
Pre-Vacuum (wrapped) Steam Sterilization Validation per ISO at 132°C with an Exposure Time of 4 minutes and a Minimum Drying Time of 20 minutes.	**Pass**
Biocompatibility Testing for both PEEK and PPSU materials according to ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation & Sensitization)	**Pass**
Electromagnetic Compatibility & Safety Testing per IEC-60601-2-2:09.2007 according to manufacture's rated voltage 3,000 V_p and tested frequency of 450 kHz.	**Pass**
Load validation of intended use during surgery.	**Pass**
Mechanical Endurance Test	**Pass**
Reprocessing Test – 100 Autoclave Cycles per DIN EN 285 at 134°C with an exposure time of 5 minutes.	**Pass**
Corrosion Resistance Testing for all Metal parts according to Boiling Test DIN EN ISO 13402.	**Pass**

Substantial Equivalence:
Integra™ Jarit® Take-Apart Endoscopic Instruments are substantially equivalent to the legally marketed predicate devices based on performance testing. The subject devices are equivalent to predicate devices with respect to intended use and materials, and design. Refer to attached predicate comparison charts 5-1A and 5-1B.

Chart 5-1A: Comparison to KNF Predicates

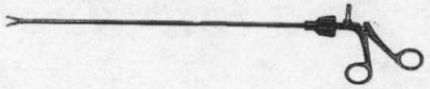
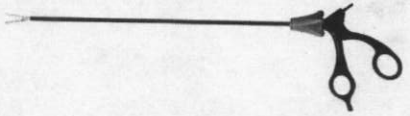
	J. Jamner Surgical Instruments Jarit Take-Apart Endoscopic Instruments	**J. Jamner Surgical Instruments** Jarit Surgical Instruments (Endoscopic Unipolar)	**Aesculap, Inc.** Modular Endoscopic Instruments
510(k) #	Subject of Submission	K932456	K010752
Class/Pro Code	II / KNF	II / KNF	II / KNF
Regulation #	884.4160	884.4160	884.4160
Classification	Coagulator-Cutter, Endoscopic, Unipolar (and Accessories)	Coagulator-Cutter, Endoscopic, Unipolar (and Accessories)	Coagulator-Cutter, Endoscopic, Unipolar (and Accessories)
Intended Use	Intended for use in laparoscopic gynecologic surgery and other operative procedures under endoscopic observations. For use when a rigid endoscopic instrument for grasping, dissecting and/or other manipulation of soft tissue is determined to be appropriate by the surgeon. For those instruments with electrosurgical capability, current can be used for coagulation and/or cutting as determined necessary and appropriate by the surgeon.	For use by, or as directed by, a surgeon in endoscopic surgery. For use when a rigid endoscopic instrument for grasping and/or dissecting of soft tissue is determined to be appropriate by the surgeon. Monopolar electrosurgical current can be used for coagulation and/or cutting as determined necessary and appropriate by the surgeon.	Intended to be used in tissue manipulation and coagulation in monopolar laparoscopic gynecology procedures.
Patient Contact Materials	Stainless Steel, PEEK, PPSU	Stainless Steel, PPSU	Stainless Steel, PEEK
Shaft Diameter	5 mm, 10 mm	5 mm, 10 mm	5 mm, 10 mm
Length	350mm, 425 mm	320mm, 370mm, 450 mm	310mm, 370mm, 420 mm
Sterility	Non-sterile	Non-sterile	Non-sterile
Sterilization	Steam Sterilizable	Steam Sterilizable	Steam Sterilizable
Utility	Reusable	Reusable	Reusable
Electrosurgical	Monopolar	Monopolar	Monopolar
	Complies with IEC 60601-2-18	Complies with ANSI / AAMI HF18-1986	Complies with IEC 60601-2-18
Handles	w/wo Rotation, w/wo Ratchets	w/wo Rotation, w/wo Ratchets	w/wo Rotation, w/wo Ratchets
Inserts	Graspers, Dissectors, Scissors, Biopsy Forceps, and Specialized Spoon Forceps Stainless Steel DIN 1.4021 (ASTM 420)	Suction Coagulators, Grasping Forceps, Scissors, Dissectors, Electrodes, Biopsy Punches, and Tissue Punches Stainless Steel DIN 1.4021 (ASTM 420)	Scissors and Forceps, Stainless Steel
Components	3 pieces - Insert, Shaft, Handle	1 piece	4 pieces - Insert, Inner Shaft, Outer Shaft, Handle
Picture of Device			

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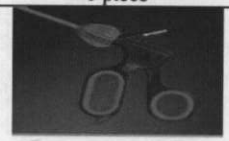
Chart 5-1B: Comparison to GEI Predicates

	J. Jamner Surgical Instruments Integra Jarit Take-Apart Endoscopic Instruments	**Applied Medical Resources** Laparoscopic Dissector	**Microline Surgical** Re-New Laparoscopic Instruments
510(k) #	Subject of Submission	K103282	K962119
Class/Pro Code	II / KNF	II / GEI	II / GEI
Regulation #	884.4160	878.4400	878.4400
Classification	Coagulator-Cutter, Endoscopic, Unipolar (and Accessories)	Electrosurgical, Cutting & Coagulation device and accessories	Electrosurgical, Cutting & Coagulation device and accessories
Intended Use	Intended for use in laparoscopic gynecologic surgery and other operative procedures under endoscopic observations. For use when a rigid endoscopic instrument for grasping, dissecting and/or other manipulation of soft tissue is determined to be appropriate by the surgeon. For those instruments with electrosurgical capability, current can be used for coagulation and/or cutting as determined necessary and appropriate by the surgeon.	For use during minimally invasive procedures for grasping, mobilizing, dissecting and cauterizing tissue.	For use for cutting and dissecting various abdominal tissue during endoscopic (inclusive of laparoscopic) surgical procedures.
Patient Contact Materials	Stainless Steel, PEEK, PPSU	Stainless Steel, Various Polymers including PEEK	Stainless Steel, PEEK
Shaft Diameter	5 mm, 10 mm	5 mm	5mm
Length	350mm, 425 mm	380mm, 450 mm	340mm, 420 mm
Sterility	Non-sterile	Sterile	Sterile and Non-sterile
Sterilization	Steam Sterilizable	Gamma Sterilizable	Steam Sterilizable
Utility	Reusable	Single Use, Disposable	Disposable/Reusable Tips Reusable Shaft/Handle
Electrosurgical	Monopolar	Monopolar	Monopolar
	Complies with IEC 60601-2-18	-	-
Handles	w/wo Rotation, w/wo Ratchets	w Rotation, wo Ratchets	w/wo Rotation, w/wo Ratchets
Inserts	Graspers, Dissectors, Scissors, Biopsy Forceps, and Specialized Spoon Forceps Stainless Steel DIN 1.4021 (ASTM 420)	Dissector Stainless Steel	Metzenbaum Scissors, Mini Scissors, Hook Scissors, Endocut Scissors, Micro Scissors Stainless Steel
Components	3 pieces - Insert, Shaft, Handle	1 piece	2 pieces – Tip Insert and Shaft/Handle
Picture of Device			

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Stephanie Sheesley
Sr. Regulatory Affairs Manager
Integra LifeSciences Corporation
589 Davies Drive
YORK PA 17402

FEB - 8 2012

Re: K103726
Trade/Device Name: Integra™ Jarit® Take-Apart Endoscopic Instruments
Regulation Number: 21 CFR§ 884.4160
Regulation Name: Unipolar endoscopic coagulator-cutter and accessories
Regulatory Class: II
Product Code: KNF
Dated: January 29, 2012
Received: February 6, 2012

Dear Ms. Sheesley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103726

Device Name: Integra™ Jarit® Take-Apart Endoscopic Instruments

Indications For Use:

Integra™ Jarit® Take-Apart Endoscopic Instruments are intended for use in laparoscopic gynecologic surgery and other operative procedures under endoscopic observations. For use when a rigid endoscopic instrument for grasping, dissecting and/or other manipulation of soft tissue is determined to be appropriate by the surgeon. For those instruments with electrosurgical capability, current can be used for coagulation and/or cutting as determined necessary and appropriate by the surgeon.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103726